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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,765	09/28/2001	Dachuan Yang	S63.2-10002	2965

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VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

BAXTER, JESSICA R

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/965,765

Applicant(s)

YANG ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02/13/02, 05/27/02, 10/25/02, 10/29/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 7, 8, 9, 12, 13, 14, 16, 18, 20 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10, 11, 15, 17, 19, 21-26 and 28-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,6,9,10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

2. Select one from each grouping.

I. Select one from:

FIG. 3,

FIG. 4,

FIG. 5,

FIG. 6,

FIG. 7,

FIG. 8,

FIG. 9,

FIG. 10 and

FIG. 11.

II. Select one from:

FIG. 12 and

FIG. 13.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 2, 10, 17 and 28-34 are generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. During a telephone conversation with James Urzedowski on June 19, 2003 a provisional election was made with traverse to prosecute the invention of FIGS 3 and 12, claims 1-4, 10, 11, 15, 17, 19, 21-26 and 28-34. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5, 6, 7, 8, 9, 12, 13, 14, 16, 18, 20 and 27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Information Disclosure Statement***

5. The information disclosure statement filed October 29, 2002 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered. It appears that a copy of Attorney Docket Number S63.2-10010 along with a declaration for this application was submitted with the IDS.

### ***Claim Objections***

6. Claim 1 is objected to because of the following informalities: In claim 1 line 5 change "at one stripe material" to --at least one stripe material--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 17 recites the limitation "the at least one sleeve" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 2, 3, 4, 10, 11, 15, 17, 19, 21, 28, 29, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,976,120 to Chow et al.

Regarding claims 1 and 34, Chow discloses a tubular catheter shaft having a distal tip comprising a matrix and at least one stripe, the matrix defined by at least one matrix material and the at least one stripe (strand 6) defined by at least one stripe material, the at least one matrix material and the at least one stripe material having a predetermined hardness, the predetermined hardness of the at least one stripe material having a greater durometer value than the predetermined hardness of the at least one matrix material (Column 4 lines 48-50).

Regarding claim 2, Chow discloses that the tubular catheter shaft defines a lumen (lumen 4).

Regarding claims 3, 11, 17 and 19, Chow discloses that the at least one stripe material is substantially parallel to a longitudinal axis of the distal tip (Column 4 lines 19-41).

Regarding claim 4, Chow discloses that the at least one stripe material has a length substantially equal to that of the matrix (Column 2 lines 43-67).

Regarding claim 10, Chow discloses that the at least one stripe material is a plurality of stripes (Column 2 lines 43-56).

Regarding claim 15, Chow discloses that each of the plurality of stripes is distributed throughout the matrix in a uniform matrix (FIGS 2-7).

Regarding claim 21, Chow discloses that the at least one stripe material is substantially enclosed by the matrix (FIGS 2-7).

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Regarding claims 28 and 29, Chow discloses that the at least one matrix material is selected from a group and the at least one stripe material is selected from a group (Column 4 lines 42-63).

Regarding claim 32, Chow discloses that the catheter is selected from the group consisting of dilatation catheters, guide catheters, over-the-wire catheters, rapid exchange catheters, and any combinations thereof (Column 6 lines 20-28).

12. Claims 1, 5, 9, 10, 12, 15, 21, 22, 23, 24, 25, 26, 32, 33 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,159,187 to Park et al.

Regarding claims 1 and 34, Park discloses a tubular catheter shaft having a distal tip comprising a matrix and at least one stripe, the matrix defined by at least one matrix material and the at least one stripe (stiffening member 206) defined by at least one stripe material, the at least one matrix material and the at least one stripe material having a predetermined hardness, the predetermined hardness of the at least one stripe material having a greater durometer value than the predetermined hardness of the at least one matrix material (Column 10 lines 1-33).

Regarding claim 10, Park discloses that the at least one stripe is a plurality of stripes (Column 8 lines 29-48).

Regarding claims 15, Park discloses that each of the plurality of stripes is distributed throughout the matrix in a uniform manner (FIGS. 3-9).

Regarding claim 21, Park discloses that the at least one stripe is substantially enclosed by the matrix (FIGS. 3-9).

Regarding claim 22, Park discloses that the matrix has an outside surface, the at least one stripe being engaged to the outside surface of the matrix (Column 10 lines 1-7).

Regarding claim 23, Park discloses that the matrix has an inside surface, the at least one stripe being engaged to the inside surface of the matrix (Column 10 lines 1-7).

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Regarding claim 24, Park discloses that the matrix layer comprises a plurality of layers, each of the plurality of matrix layers being a different material (Column 1-33).

Regarding claims 25 and 26, Park discloses that the plurality of matrix layers comprise an inner and outer matrix layer, wherein the at least one stripe is positioned between at least a portion of the inner layer matrix layer and the outer matrix layer (Column 10 lines 1-33).

Regarding claim 33, Park discloses that at least a portion of the tip is radiopaque (Column 11 lines 42-47).

### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow et al. '120 or Park et al. '187.

Chow and Park disclose the claimed invention except for the hardness of the matrix material and the at least one stripe material. Chow and Park disclose the same materials as claimed. It would have been an obvious matter of design choice to change the hardness of the material to suit the particular needs of the surgical procedure for which the catheter is used, since such a modification would have involved the mere change in hardness of a material. The change in hardness is generally recognized as being within the level of ordinary skill in the art.

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***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,136,006 to Johnson et al.

U.S. Patent No. 6,503,353 to Peterson et al.

U.S. Patent No. 6,554,841 to Yang

US PG-PUB 2002/0038140 to Yang et al.


US PG-PUB 2002/0038141 to Yang et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

  
jrb  
June 30, 2003

  
MICHAEL J. MILANO  
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